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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/549,384

11/03/2005

Paul Leonard Greenhaff

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03/18/2010

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EXAMINER

KRISHNAN, GANAPATHY

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/549,384	Applicant(s) GREENHAFF ET AL.	
	Examiner Ganapathy Krishnan	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 112-162 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 112-162 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A Request for Continued Examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed 9/25/2009 was entered.

Applicants Request for Continued Examination filed 9/25/2009 included a request for suspension of action on this application for a period of three months, until December 25, 2009. An Office Action on the merits of the then pending claims 58-111 (claims 1-57 cancelled in preliminary amendment) was inadvertently mailed on December 15, 2009 before the conclusion of the suspension period. Hence, the Office Action mailed December 15, 2009 has been vacated and an Action on the merits of the instant pending claims contained herein below is made of record.

The amendment filed 12/22/2009 has been received, entered and carefully considered. The following information has been made of record in the instant amendment:

1. Claims 1-111 have been canceled.
2. New Claims 112-162 have been added.
3. Remarks drawn to rejections under 35 USC 103 of record.

The following rejections have been overcome:

4. The rejection of Claims 58-63, 76-80 and 91-92 are rejected under 35 U.S.C. 102(b) as being anticipated by Davis et al (EP 0680945); The rejection of Claims 58-65, 74, 76-83, 91 and 93-102 are rejected under 35 U.S.C. 102(b) as being anticipated by Pola (WO 01/95915, of

Art Unit: 1623

record); The rejection of Claims 93-103 are rejected under 35 U.S.C. 102(b) as being anticipated by Bohles et al (J. Parenteral and Enteral Nutrition, 1984, 8(1), 9-13, of record) and the rejection of Claims 93-103 are rejected under 35 U.S.C. 102(b) as being anticipated by Gross et al (Biochim. Biophys. Acta., 1993, 1170(3), 265-274, of record) have all been rendered moot by cancellation of the said claims

Claims 112-162 are pending in the case.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 112-118, 120-134, 136-150 and 152-162 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising L-carnitine and glucose, sucrose or fructose, and amino acids and the method of increasing carnitine retention using the said composition, does not reasonably provide enablement for a composition comprising any other agent and its use in the method as instantly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

Art Unit: 1623

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without *undue experimentation*. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- (1) The nature of the invention
- (2) The state of the prior art
- (3) The relative skill of those in the art
- (4) The predictability or unpredictability of the art
- (5) The breadth of the claims
- (6) The amount of direction or guidance presented
- (7) The presence or absence of working examples; and
- (8) The quantity of experimentation necessary.

The most relevant factors are discussed below.

The nature of the invention

The instant invention pertains to compositions comprising a carnitine substance and an agent to increase blood/plasma insulin concentration and method of increasing carnitine retention in animal or human skeletal muscle using the said composition.

The breadth of the claims

Instant claims 112, 128 and 144 and dependent claims thereof recite the terms, an agent to increase blood/plasma insulin concentration and carbohydrates, proteins and amino acids. The recitation, ‘an agent to increase blood/plasma insulin concentration’ is functional language. The recitations are broad and are seen to include any substance as agent and any carbohydrate, protein or amino acid including synthetic proteins.

The amount of direction provided or guidance presented by the inventor

Art Unit: 1623

The instant specification (page 5, 15-18) teaches that the agent can be carbohydrate or a derivative of carbohydrate but the claim recitation is seen to include substances other than carbohydrates. Even the term carbohydrate is broad and is seen to include any carbohydrate. Proteins and amino acids are not seen in the definition. The amounts recited for the agents are also very high.

The level of Predictability or Unpredictability in the Art

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed. Prior art used in the rejections below, teaches the use of L-carnitine, its acyl derivative, amino acids and ribose in addition to glucose, fructose and sucrose. The art is silent regarding the use of any other sugar/carbohydrate and protein. Based on the teachings of the prior art it is highly unpredictable that the instant compositions comprising any carbohydrate and protein in the high amounts recited can be used in the methods as instantly claimed. The instantly claimed invention is highly unpredictable.

The presence or absence of working examples

The working examples set forth in the instant specification are drawn to the use of L-carnitine and glucose as the agent. One of ordinary skill in the art will not be able to figure out what other carbohydrates and proteins can be used in the instant composition to perform the functions as claimed. Thus, the specification fails to provide clear and convincing evidence in sufficient support of for the active agents and their use in the method as recited in the instant claims. As a result, it necessitates one of skill to perform an exhaustive search for the embodiments of using any carbohydrate or protein as recited in the instant claims suitable to practice the claimed invention.

Art Unit: 1623

The quantity of experimentation needed to make or use the invention based on the content of the disclosure

Indeed, in view of the information set forth, the instant disclosure is not seen to be sufficient to enable the compositions and methods of use as broadly encompassed by the recitation in the instant claims. One of ordinary skill in the art would have to carry out undue experimentation to practice the instant invention.

Genentech, 108 F.3d at 1366, states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable”.

Therefore, in view of the Wands factors discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation, with no assurance of success.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 112-162 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 112 recites the terms, ‘an agent’. The specification (page 5, 15-18) teaches that the agent can be carbohydrate or a derivative of carbohydrate but the claim recitation is seen to include substances other than carbohydrates. The metes and bounds of the said terms recited in this and all other claims in which the said terms are recited, are unclear.

Art Unit: 1623

The term "simple" in claim 117 is a relative term which renders the claim indefinite. The term "simple" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The specification gives examples of simple carbohydrates but the degree of simplicity is not clear from these examples either. The said term is also recited in other claims.

Claim 160 recites administering a composition according to claim 112 but it is not clear to who or what the said composition is administered.

Claims 113-116 and 118-159 and 161-162 which depend from rejected base claims that are unclear/indefinite are also rendered unclear/indefinite and are rejected for the same reasons.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 112-162 are rejected under 35 U.S.C. 102 as being anticipated by Pola (WO 01/95915, of record).

Pola teaches a composition comprising L-carnitine (250mg), ribose (1g), dextrose (misspelled as destrose; another name for glucose; 0.5g), fructose (0.5g). In this composition ribose, dextrose and fructose are the agents for increasing the blood/serum insulin concentration (as recited in instant claims 116-119; 132-135; 148-151). In the composition of Pola the total

Art Unit: 1623

amount of the carbohydrates, ribose, dextrose and fructose (the agent) is 2g. L-carnitine is 250mg, which 0.25g. Hence, the ratio of the agent to the L-carnitine by weight is 10:1 (limitations of instant claims). Instant claims 113-114 and 144 recite the term, 'wherein'. This recitation is interpreted as intended use and the disclosed compositions comprising the components as instantly claimed is seen to be capable of meeting the intended use. MPEP 2112.01 providing "A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)". The sugars disclosed by Pola are seen to possess the claimed properties inherently. Pola teaches administration of his composition to an individual. Since the composition of Pola comprises the active agents instantly claimed, it possesses the properties of the instant composition and would have the same effects as claimed in instant method claims 160 and 162.

Response to Applicants Arguments

Applicants have argued the art rejection under 35 USC 103(a) of record. In response the art rejection above is made of record.

Conclusion

Claims 112-162 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

Art Unit: 1623

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ganapathy Krishnan/
Examiner, Art Unit 1623

/Shaojia Anna Jiang/

Supervisory Patent Examiner, Art Unit 1623